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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,876	04/11/2005	Dieter Dorsch	MERCK-2998	2264

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
CHENG, KAREN	
ART UNIT	PAPER NUMBER
1626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,876	DORSCH ET AL.	
	Examiner	Art Unit	
	Karen Cheng	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *21 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 22* is/are rejected.

7)☒ Claim(s) *1-20 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are currently pending in the instant application. Claims 1-20 (in part), 21, 22 (in part) and 23 are withdrawn from consideration as being non-elected subject matter.

Response to Election/Restrictions

Applicant's election with traverse of the subject matter of claims 1-15 and 17-20, drawn to compounds of formula I and/or pharmaceutically usable derivatives, solvates, and stereoisomers thereof, wherein X is NR^3, R^1 is A which is an unbranched or branched alkyl having 1-10 C atoms, Y is Ar-diyl, D is a thienyl ring which is mono- or disubstituted by Hal, T is morpholin-4-yl which is monosubstituted by carbonyl oxygen(=O), and W is as defined in the reply filed on 11/01/2006 is acknowledged. The traversal is on the ground(s) that the Examiner has not established that search of the full scope of the claims would constitute a search burden. This argument is not found persuasive because, although it is obvious on its face that search of the full scope of the claims would constitute a search burden (see for example the definition of Het found in the claims), the Examiner has only to establish that unity of invention is lacking in this application since it is a 371 of an international application. The Examiner has, in fact, established that unity of invention is lacking. The requirement is still deemed proper.

Examiner has considered Applicants request to rejoin Group VI, drawn to a method of making compounds of formula I (claim 16), and composition claims 19, 20, and kit claim 22 to the currently pending claims and to broaden the search beyond what was elected. Examiner has expanded the search so that compounds of formula I

wherein X is NR^3, R^1 is as defined, Y is cycloalkylene, Het-diyl or Ar-diyl, D is a thienyl ring which is mono- or disubstituted by Hal, A, OR^2, $N(R^2)_2$, NO_2, CN, $COOR_2$ or $CON(R^2)_2$, and T and W are as defined have been fully examined. Additionally, claims 16-20 and 22 have been rejoined to the compound claims 1-15 and examined.

Priority

The application is a 371 of International Application No. PCT/EP03/10400, filed on 09/18/2003, which claims the benefit of foreign priority under 35 U.S.C. 119, to German Application No. 10247226.2, filed on 10/10/2002.

Information Disclosure Statement

Applicant's Information Disclosure Statement filed on 4/11/2005 has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112 – 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 16, 19-20 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of some of the compounds of the formula described in the instant claim 1, does not reasonably provide enablement for compounds having the formula I and the "pharmaceutically usable derivatives". The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*. 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

The nature of the invention

The nature of the invention is compounds, a process of preparation, and medicaments of formula I and pharmaceutically usable derivatives.

The state of the prior art and the predictability or lack thereof in the art

Since the compounds as claimed are reported to be novel, there should not be any prior art that disclose such compounds or preparation of such compounds.

The term "derivative" found in the claims is defined as a compound, usually organic obtained from another compound by a simple chemical process or a organic compound containing a structural radical similar to that from which it is derived (Hackh's chemical dictionary, 1972).

The existence of these obstacles establishes that one of ordinary skill in the art would not know what chemical structures are encompassed by the term "pharmaceutically usable derivatives". In the instant case, the specification does not provide guidance as to how one skilled in the art would ascertain what would be considered an appropriate substitution to make for a "pharmaceutically usable derivatives".

The amount of direction or guidance present and the presence or absence of working examples

The specification does not provide working examples in which a pharmaceutically usable derivative is synthesized. It does not provide direction for the preparation of any a pharmaceutically usable derivative of the compound of formula I. Since the chemical moieties encompassed by these terms are variable in reactivity, it cannot be said with absolute certainty such compounds can be prepared through the same route as compounds of formula I.

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include compounds of formula I and "pharmaceutically usable derivatives." Thus, multiple derivatives of the compounds of formula I having various functional groups and chemical reactivity are encompassed by the instant claims. However the specification only provides evidence for compounds of formula I, and does not provide examples of the "pharmaceutically usable derivatives."

The quantity or experimentation needed and the level of skill in the art

It would require undue experimentation of one of ordinary skill in the art to ascertain what could be considered pharmaceutically usable derivatives. Factors such as "sufficient working examples", "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant compound claims. One would need to prepare compounds with similar structural radicals and/or biological activity without any direction as to what structural radical is needed and how different the derivative can be from the compound of the formula (I). In view of the breadth of the claims, the chemical nature of the invention and the lack of working examples regarding the process as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in cope with the claims.

In consideration of each of the 8 factors, it is apparent that undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent

factual data to the contrary, the amount and level of experimentation needed is undue. Therefore, claims 1-14, 16, 19-20 and 22 are rejected under 35 U.S.C. § 112, 1st paragraph. These rejections can be overcome by deletion of the phrase "pharmaceutically usable derivatives" or replacement with a more descriptive term such as "pharmaceutically acceptable salts."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 20 and 22 recites the limitation "at least one further medicament active ingredient." On p. 6-7 of the specification, it is stated that the compound can be employed with other thrombolytically active compounds or blood platelet glycoprotein receptor (Iib/IIIa) antagonists, but the specification does not state if these compounds are what is considered "one further medicament active ingredient" and fails to define the term or teach exactly what is meant by "one further medicament active ingredient." If a blood platelet glycoprotein receptor (Iib/IIIa) antagonist can be considered "one further medicament active ingredient," the specification does not define how to determine what can or cannot be considered a blood platelet glycoprotein receptor (Iib/IIIa) antagonist. Thus, "at least one further medicament active ingredient" is not defined so as to know the metes and bounds of the claims. Therefore claims 20 and 22 are rejected.

Claim Objections

Claims 17 and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). A compound's intended use does not further limit the claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 1-20 (in part) and 22 (in part) are objected to because of the following informalities: they are dependent on subject matter that has been withdrawn from consideration. Deletion of subject matter outside the scope of search is required.

Objections: Content of Specification

The specification does not incorporate cross reference to related applications. The specification should contain the following sections below, as applicable:

b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Karen Cheng
Patent Examiner, AU 1626

Joseph McKane
Supervisory Patent Examiner, AU 1626